510(k) Summary

K100274

MAY 10 2010

Date Prepared:	January 28, 2010
Submitter:	Medtronic 7611 Northland Drive Minneapolis, MN 55428 Establish Registration Number: 2184009
Contact Person:	Caralee Walton Senior Regulatory Affairs Specialist Phone: (763) 514-9851 Fax: (763) 367-8360 Email: caralee.a.walton@medtronic.com

Device Name and Classification

Trade Name:	MiAR™ (Minimally Invasive) Aortic Root Cannula with Flow-Guard™
Common Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Classification:	Class II

Predicate Devices

Medtronic DLP Aortic Root Cannula (K790565)
Medtronic Pediatric Aortic Root Cannula (K040173)

Device Description

MiAR™ Cannulae are single-use, sterile, nonpyrogenic devices designed to deliver cardioplegia through the aorta in an antegrade manner, for periods up to six hours during cardiopulmonary bypass surgery. These devices are available in models that feature two tip sizes and the Flow-Guard™ feature to maintain hemostasis during removal of the introducer needle from the cannula. The increased overall length of these cannulae relative to standard models, make them easier to use when minimally invasive surgical approaches are utilized (i.e., mini-sternotomy and right thoracotomy).

Indications for Use

The MiAR™ cannula is intended for use during cardiopulmonary bypass for the delivery of cardioplegia for up to 6 hours. The cannula may also be used to aspirate air from the aorta at the conclusion of the bypass procedure. It is indicated for use during cardiac surgery for median sternotomy or minimally invasive (mini-sternotomy or right thoracotomy) access using direct visualization techniques.

Comparison to Predicate Devices

A comparison of the modified product and the currently marketed Aortic Root Cannula indicates the following similarities to the device which received 510(k) clearance:

- Same technological characteristics
- Same operating principle
- Same design features, only longer length
- Same Flow-Guard™ introducer
- Same connectors
- Same materials
- Same shelf life

Summary of Performance Data

Bench testing was used to establish the performance characteristics of the modifications of this device from previously marketed Medtronic cannula devices. Clinical testing was not required to establish substantial equivalence. The following performance tests were conducted:

- Flow Rate Versus Pressure Drop
- Distal tip visibility Under Fluoroscopic Visualization
- Structural Integrity (bonded joints)

Conclusion

Medtronic has demonstrated that the MiAR™ Cannulae are substantially equivalent to the predicate device based upon design and test results. Any noted differences do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAY 10 2010

Medtronic, Inc.
c/o Ms. Caralee A. Walton
Senior Regulatory Affairs Specialist
710 Medtronic Parkway NE
Minneapolis, MN 55432

Re: K100274
MiAR™ (Minimally Invasive) Aortic Root Cannula with Flow-Guard™
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: II
Product Code: DWF
Dated: May 3, 2010
Received: May 4, 2010

Dear Ms. Walton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Richmond

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100274

Device Name: MiAR™ Aortic Root Cannula with Flow-Guard™

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100274